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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,178	07/18/2003	Yoshihiro Mori	09496/000M861-US0	2675

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EXAMINER	
DEAK, LESLIE R	
ART UNIT	**PAPER NUMBER**
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,178	MORI ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 November 2006 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-4,14-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,539 to Maynard in view of US 5,291,884 to Heinemann.

In the specification and figures, Maynard discloses the apparatus and method substantially as claimed by applicant. With regard to claim 1, Maynard discloses a hematocrit sensor within a blood circuit that comprises a plasma separation system that may be used to "purify" the blood for reinfusion to the patient (see column 3, lines 10-39). The sensor is located in a housing 90 with a slot in bottom half 124 for optical connector and hollow member 100, 102. The slot further comprises a slit or window

106, and light emission means and detection means 54, 56, 58 that all face the hollow member from the same side of the housing (see FIGS 9, 10, column 12, lines 22-39, column 11, lines 20-40, column 7, lines 45-50, column 8, lines 41-59).

Maynard fails to disclose that the apparatus comprises a light emission device and a single light reception device in optical connection with one another. Heinemann discloses a hematocrit sensor that may comprise a single light source and detector (see column 2, lines 20-23, 37-40). The source and detector face the blood passage from the same direction via apertures 21 and 23 (see FIG 1). In operation, the device emits light from source 29, and the detector 31 receives light that is reflected back from the sample (see column 1, lines 40-46, column 5, lines 40-53). The light received by the detector 31 is used to calculate the hematocrit value of the blood passing by the sensor. Since the light source emits light and a single detector receives light, the emitter and detector are in optical connection with one another (see column 2, lines 20-23, 37-40). Heinemann discloses that a single detector is preferred for ratioing purposes. Therefore, it would have been obvious to provide the blood purification apparatus with hematocrit detection system disclosed by Maynard with the light emitter and single light receptor for ratioing purposes, as taught by Heinemann.

With regard to claims 2-4, Maynard discloses that the housing 90 comprises a lid 120 connected to the housing by hinge 126 and a locking arm 122 that holds the cover in place (see Maynard FIG 9).

With regard to claims 14, 16, and 17, Maynard discloses that the light emitter provides light in the direction of blood flowing through the tube 102, the detector detects

the amount of light back-scattered against the blood sample, determining the amount of light reflected, and generating a signal reflective of the hematocrit in the blood sample based on the amount of reflected light (see column 9, lines 18-55). The device disclosed by Heinemann also uses back scattered light received by the single detector to determine hematocrit levels in the blood, indicating that the substitution of the single detector as disclosed by Heinemann would function the same as the Maynard device with two detectors. In an embodiment of the Maynard device, the sensor is connected to a microprocessor that calculates hematocrit values and regulates the operation of the extracorporeal circuit based on the calculated hematocrit value (see column 13, lines 10-23). The hematocrit sensor disclosed by Maynard functions when the light source is pulsed (see column 9, lines 14-16), and may be used to signal the beginning or the end of a transfusion cycle (see column 13, lines 43-50). The sensor further comprises a method for calibrating the light coming from the emitter, when compared against a reference value, in order to compensate for changing conditions in the sample area, which may include blood flow rate (see column 9, lines 35-46).

With specific regard to claim 15, The Heinemann device may provide light pulses, wherein a signal is measured during the light emission pulse and then corrected with the use of a baseline signal that accounts for ambient light seen be the detector (see column 6, lines 56-68, column 7, lines 1-8).

4. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,539 to Maynard in view of US 5,291,884 to Heinemann, further in view of US 5,838,429 to Hahn et al.

In the specification and figures, Maynard and Heinemann disclose the device substantially as claimed by applicant (see rejection above) with the exception of a device configured to detect whether the circuit, comprising the sensor, is in the slot and whether the door is closed. Hahn discloses an apparatus for measuring the physiological parameters of blood in extracorporeal circulation comprising a blood circuit and a light sensor 2 enclosed in a cavity 3. The cavity comprises a cover 7 and a detector 8 that detects when a circuit tube is missing or the cover is opened. The detector allows for the interruption of light emission and erroneous detection signals if the cover is opened (see column 4, lines 3-8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a tube/cover detector as disclosed by Hahn to the hematocrit sensor system disclosed by Maynard and Heinemann in order to prevent erroneous readings when the tube is missing or cover is opened, as taught by Hahn.

5. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,539 to Maynard in view of US 5,291,884 to Heinemann, further in view of US 6,582,385 to Burbank et al.

In the specification and figures, Maynard and Heinemann disclose the device substantially as claimed by applicant (see rejection above) with the exception of a pump, substitution fluid, and a dialyzing fluid. Maynard specifically discloses, however, that his hematocrit sensor may be deployed in any extracorporeal blood circuit, which may include a dialysis circuit, in order to control the progress of the blood through the circuit based on the measured hematocrit value (see column 4, lines 11-23).

Burbank discloses a dialysis system with pump 20 that passes blood to a hemofilter, ultrafiltrate pump 47, replacement fluid, dialysis fluid, a drip chamber, flow detector, blood leak detector that may detect the presence of blood in a segment of the circuit, and an air bubble detector (see columns 6-8, column 15). The drip chamber may be connected or fixed to a hematocrit sensor that may, in turn, control the operation of the extracorporeal circuit. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the extracorporeal system with hematocrit sensor disclosed by Maynard and Heinemann with the extracorporeal dialysis circuit disclosed by Burbank to operate with the prior art hematocrit sensor in order to allow the sensor to control the extracorporeal circuit, as taught by Maynard.

6. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,539 to Maynard in view of US 5,291,884 to Heinemann, further in view of US 4,082,461 to Mould.

In the specification and figures, Maynard and Heinemann disclose the device substantially as claimed by applicant (see rejection above) with the exception of an adjustable slit or pore size. Mould discloses a photodetection system with an adjustable slit or pore size in order to control the slit width in accordance with certain operational requirements (see column 1, lines 5-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the openings adjustable, since it has been held that the provision of adjustability, where needed (as

demonstrated by the Mould reference), involves only routine skill in the art. See MPEP § 2144.04.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,385,539 to Maynard in view of US 5,291,884 to Heinemann, further in view of US 6,554,788 to Hunley et al.

In the specification and figures, Maynard and Heinemann disclose the method substantially as claimed by applicant (see rejection above) with the exception of detecting hematocrit values as soon as blood starts flowing through the circuit. However, Hunley discloses a hematocrit measurement system that begins measuring hematocrit values immediately after the circuit responds to the presence of blood in the circuit, and evaluating the early hematocrit values to assess them for errors. The immediate hematocrit detection allows for the measurement of hematocrit levels of very small volumes of blood without data loss (see column 2, lines 29-67, column 3, lines 1-57). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the step of immediately begin measuring hematocrit as soon as blood enters the circuit, as taught by Hunley, to the hematocrit measurement system and method disclosed by Maynard and Heinemann, in order to minimize data loss, as taught by Hunley.

Response to Arguments

8. Applicant's arguments, see RCE, filed 1 November 2006, with respect to the rejection(s) of claim(s) 1-4, 14, 16, and 17 under 35 UCS 102 (b) as anticipated by

Maynard have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Maynard and Heinemann.

9. Applicant's arguments with regard to the Heinemann device have been fully considered but they are not persuasive. Applicant argues that the Heinemann device discloses an optical wall 25 between the light emitter and the light detector, which is not required by the instant invention. However, such a recitation is not present in the claims. Furthermore, omission of an element and its function is obvious if the function of the element is not desired. See MPEP 2144.04 (II). In the instant case, applicant has not set forth any structural limitations that distinguish the instantly claimed invention from the prior art nor demonstrated how his device specifically excludes the optical wall set forth in the prior art. Therefore, the device is unpatentable over the prior art.

Furthermore, applicant uses "comprises" language when setting forth the structural limitations of the claimed device and method. According to MPEP 211.03, the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004). "The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps." Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Therefore, the presence of an optical wall 25 in the device disclosed by Heinemann does not render the instantly claimed invention unobvious, since the

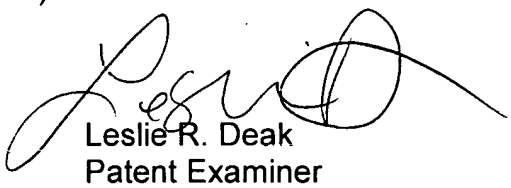
instantly claimed invention may include additional, unrecited elements, such as Heinemann's optical wall.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
21 December 2006